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10/579,146	02/22/2007	Michael Mahoney	101896-0474	8927
21125 7590 03/19/2010 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
WAGGLE, JR, LARRY E				
ART UNIT		PAPER NUMBER		
3775				
NOTIFICATION DATE		DELIVERY MODE		
03/19/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

# Office Action Summary

Application No.

10/579,146

Applicant(s)

MAHONEY ET AL.

Examiner

Larry E. Waggle, Jr

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-48 and 59-62 is/are pending in the application.
- 4a) Of the above claim(s) 12-13, 19, 22-23, 35-43 and 59-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-18, 20-21, 24-34 and 44-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 Jan 2010 and 12 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 13 January 2010
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 46a and 46b, as disclosed on page 13, line 7; and 505, as disclosed on page 17, line 12. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 9 – 143 and 151; Figure 10 – 110, 112b, 122a, 143 and 152; Figure 11 – 110, 112b, 122a, 143 and 152; Figure 12 – 241 and 243; Figure 13 – 222b, 241 and 242; Figure 14 – 314; Figure 15 – 314, 333c, 341 and 343; Figure 16 – 314, 333c, 341 and 343; Figure 17 – 314, 322a and 341; Figure 18 – 422, 441 and 442; Figure 19 – 422; Figure 20 – 422, 441, 442 and 443; Figure 21 – 522; Figure 22 – 522, 541, 542 and 543; Figure 23 – 522; Figure 24 – 641; Figure 25 – 641 and 643; Figure 26 – 641;

Figure 27 – 712, 741 and 742; Figure 28 – 741 and 742; Figure 34 – 942; Figure 35 – 942; Figure 36 – 1352; Figure 37 – 1041; Figure 39 – 1181a and 1181b; Figure 40 – 1246 and 1248; Figure 41 – 1246 and 1248; Figure 42 – 1311, 1341, 1342 and 1380; and Figure 43 – 1311, 1341, 1342, 1343 and 1380. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "the means for preventing migration" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

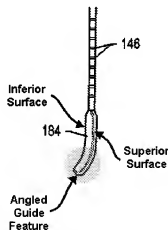
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 20-21 and 27-29** are rejected under 35 U.S.C. 102(e) as being anticipated by Webb (US Publication 2005/0027360).

Webb discloses a surgical instrument system (Figures 13A and 13B) comprising an instrument (182) capable of maintaining a distraction between vertebrae including a shaft (186) and a paddle (184) having inferior and superior surfaces (see annotated

Figure below) located on a distal end of the shaft; an implant inserter (190) having a distal end (i.e. tip of 192); and an access port (paragraph 0081), wherein the paddle and shaft present a guide surface (i.e. left surface of 184 as shown in Figure 10) and a guide feature (i.e. left surface of 186 as shown in Figure 10) for guiding the placement of the implant and interaction with the distal end of the inserter and an angled guide feature (see annotated Figure below) integral with the distal portion of the paddle to guide an implant (100) through a partial rotation to a desired angle and the paddle includes a first height (i.e. width of left surface of 184 as shown in Figure 10) and a second height (i.e. thickness of 184 as shown in Figure 13A) greater than the first height (Figures 10-13D and paragraphs 0072-0090).



With regard to the statements of intended use and other functional statements, such as “for” and “configured to,” they do not impose any structural limitations on the claims distinguishable over Webb which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the

reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

**Claims 44 and 45** are rejected under 35 U.S.C. 102(b) as being anticipated by Han et al. (WO 02/17823 A1).

Lim discloses a surgical instrument system (Figure 12) comprising an articulating implant inserter including a shaft (172) and an articulatable implant holding element (162) located on a distal end of the shaft operable from a proximal portion of the shaft to releasably hold (i.e. via 174) an implant (30), wherein the implant has a connecting element (46) internal to the implant that cooperates with the holding element to allow articulation of the implant to a desired angle, and the holding element includes two sliding elements (166/168 and 172) operable from a proximal handle (130) to provide the articulation of the implant to the desired angle (Figures 5 and 11-13 and page 14, line 26 – page 17, line 5).

**Claims 44 and 46-48** are rejected under 35 U.S.C. 102(e) as being anticipated by Lim (US Publication 2004/0153065).

Lim discloses a surgical instrument system (Figure 10) comprising an articulating implant inserter (9) including a shaft (80) and an articulatable implant holding element (55) located on a distal end of the shaft operable from a proximal portion of the shaft to

releasably hold (i.e. via 90) an implant (10), wherein the implant has a connecting element (93) external to the implant that cooperates with the holding element to allow articulation of the implant to a desired angle, and the holding element includes two sliding elements (81 and 82) having distal implant impaction faces operable from a proximal handle (130) to provide the articulation of the implant to the desired angle (Figures 10-16 and paragraphs 0035-0061).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-11, 15, 17-18 and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Nichols et al. (US Publication 2003/0149438).



Webb discloses the claimed invention except for a filler bar to removably engage the shaft and paddle of the distractor, wherein the filler bar extends substantially along at least one side of the shaft and paddle, does not extend beyond the superior and inferior surfaces of the paddle and slidably engages the distractor along a longitudinal axis of the distractor. Nichols et al. teach an instrument (30) capable of maintaining a distraction between vertebrae including a shaft (31) and a paddle (25) and a filler bar (12) shaped to removably engage (i.e. by sliding) the shaft and paddle of the distractor (Figure 2 and paragraphs 0027-0031). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the instrument capable of maintaining a distraction between vertebrae including a shaft and a paddle and a filler bar shaped to removably engage the shaft and paddle of the distractor in view of Nichols et al. in order to provide a safe and secure means for inserting an implant.

Webb in view of Nichols et al. disclose the claimed invention except for at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) to prevent the migration of the distractor during distraction. Webb discloses the implant (100) having protrusions / teeth / expansion shoulders (130) (Figure 3 and paragraph 0044). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb in view of Nichols et al. with at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion

shoulder) in order to penetrate the vertebral plate to inhibit the removal of the distractor during distraction.

Webb in view of Nichols et al. disclose the claimed invention except for the distal end of the inserter being angled to correspond with the angle of the angled guide feature. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb in view of Nichols et al. with the distal end of the inserter being angled to correspond with the angle of the angled guide feature in order to provide mating guide surfaces between the distractor and the inserter to reduce the overall profile of the combination, since the applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an angled distal end. In re Dailey and Eilers, 149 USPQ 47 (1966).

**Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Nichols et al. (US Publication 2003/0149438) further in view of Frey et al. (US Publication 2002/0165550).

Webb in view of Nichols et al. disclose the claimed invention except for the angled guide feature being formed from a shape memory material. Frey et al. teach an inner shaft (226) of an instrument (220) being formed from nitinol (Figure 11 and paragraph 0104). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb in view of Nichols et al. with the angled guide feature being formed from nitinol in view of Frey et al. in order

to provide a flexible feature for ease of manipulation when guiding through the access port and the intervertebral space.

**Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Nichols et al. (US Publication 2003/0149438) further in view of Lim (US Publication 2004/0153065).

Webb in view of Nichols et al. disclose the claimed invention except for the inserter having an articulating implant holder. Lim discloses an inserter (9) having an articulatable implant holding element (55) (Figures 11 and 12 and paragraphs 0035-0061). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb in view of Nichols et al. with the inserter having an articulatable implant holding element in order to precisely place the implant between vertebrae at a desired angle.

**Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Frey et al. (US Publication 2002/0165550).

Webb discloses the claimed invention except for the angled guide feature being formed from a shape memory material. Frey et al. teach an inner shaft (226) of an instrument (220) being formed from nitinol (Figure 11 and paragraph 0104). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the angled guide feature being formed from nitinol in view of Frey et al. in order to provide a flexible feature for ease of manipulation when guiding through the access port and the intervertebral space.

**Claims 25 and 30-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360).

Webb discloses the claimed invention except for the distal end of the inserter being angled to correspond with the angle of the angled guide feature. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the distal end of the inserter being angled to correspond with the angle of the angled guide feature in order to provide mating guide surfaces between the distractor and the inserter to reduce the overall profile of the combination, since the applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an angled distal end. In re Dailey and Eilers, 149 USPQ 47 (1966).

Webb discloses the claimed invention except for at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) to prevent the migration of the distractor during distraction. Webb discloses the implant (100) having protrusions / teeth / expansion shoulders (130) (Figure 3 and paragraph 0044). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) in order to penetrate the vertebral plate to inhibit the removal of the distractor during distraction.

**Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Lim (US Publication 2004/0153065).

Webb discloses the claimed invention except for the inserter having an articulating implant holder. Lim discloses an inserter (9) having an articulatable implant holding element (55) (Figures 11 and 12 and paragraphs 0035-0061). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the inserter having an articulatable implant holding element in order to precisely place the implant between vertebrae at a desired angle.

#### ***Response to Arguments***

Applicant's arguments, see pages 13-16, filed 13 January 2010, with respect to the rejection(s) of claim(s) 1, 20-21, 25-28, 44, 49, 52 and 54-58 under 35 U.S.C. 102(b) and claim(s) 2-11, 14-18, 24, 29-34, 45, 47-48, 51 and 53 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the prior art used in the rejections above.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is 571-270-7110. The examiner can normally be reached on Monday through Thursday, 6:30am to 5pm, EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Larry E Waggle, Jr/  
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